December 4, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00D-1539; Draft Guidance for Industry, Electronic Records: Electronic Signatures, Maintenance of Electronic Records

Dear Sir/Madam:

Schering-Plough has reviewed the Draft Guidance for Industry, Electronic Records: Electronic Signatures, Maintenance of Electronic Records, and we offer the following comments for your consideration.

1. As an overall comment we feel that the approach taken in this draft guidance is too general in that there is no distinction made between data and documents as types of records and there is no distinction in the type of retention; i.e., operational accessibility versus "snapshot" long-term archival. Static non-editable records of original raw data bearing the manifestation of e-signature should suffice for long-term archival, while processable records would be maintained during shorter periods where re-processing may occur as part of inspection or re-use.

2. Section 5.3 *Continued Availability and Readability of Electronic Record Information Should be Assured* is too vague. We suggest that refreshment schedules be established based on proven media longevity. We also suggest backing up all records for the length of the retention using three copies and two different media, each stored separately.

3. The requirements in Section 5.5 *The Ability to Process an Electronic Record's Information Throughout its Records Retention Period Should be Preserved* would be difficult to implement for long retention periods. It would mean anticipating all future uses of data and documents. This level of functionality should be requested only during short periods where the records are kept live.

4. With regard to the time capsule approach discussed in section 6.1 *The Time Capsule Approach*, maintaining inactive systems while ensuring that they are capable of working, as well as training personnel on old systems that are not used

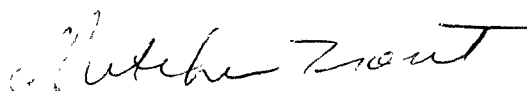OOD-1539   C 10

is impractical. We propose that the time capsule approach be replaced with a live system solution.

5.   Section 6.2 *The Electronic Records Migration Approach* suggests that companies might want to consider not discarding old electronic records or systems once records have migrated to new systems. Based on the fact that most migrations occur due to inability to operate the old system based on hardware/software aging, or the loss of knowledge on how to run the system, retaining the old system may not be a viable option. An alternative would be to store the original raw data in a static form.

6.   We have several comments on Section 6.2.1.2 *Factors in the New Computer System That Enable the Electronic Record to Reliably Preserve and Present Information Should be Identified and Controlled.*

    a.   Migrating to new systems with different dictionaries while preserving the complete and accurate description of old data is not always possible.

    b.   Controlling operating systems is outside the scope and ability of the users.

    c.   The level of control required in this and the following sections can only be achieved for live systems.

    d.   Identical results can be achieved only if archived records are static.

    e.   When migrating databases from old to new systems, mapping of the data is often required. It should be ensured that the new system presents information that is consistent with the initial database.

7.   With regard to section 6.2.1.3 *Electronic Record Integrity Attributes Should be Preserved,* migration to new systems should either apply to live tools or to static records that bear a human readable manifestation of audit trail and e-signatures. Audit trail of the migration itself should in this case be generated and attached to the new records.

8.   With regard to section 6.2.1.4 *The Ability to Process Information in Electronic Records Should be Preserved,* the ability to process can reasonably be ensured only in live systems and for limited retention periods. Ensuring that a new system has equal or greater capacity to process old data is beyond the scope of users, and in any case unforeseeable. Instead, we propose the archival of raw initial data in static format. If re-processing becomes a need, a new system could be used to do the analysis.

9.   Section 6.2.1.5 *Unavoidable Differences and Losses Should be Accounted For and Explained in the Migrated Electronic Record or New System Documentation* contradicts the previous section and implicitly acknowledged that, in many cases,

they are not going to be applicable. The steps for ensuring continuity of e-signature across the migration gabs are convoluted and difficult to understand. The example with color code is even more complex and contradictory; e.g., the colors in the new record have changed because of system differences but are considered "not altered" while changing the text describing them would be an alteration. The examples in the draft guidance illustrate the limits of archiving and migrating dynamic records across a changing technical environment. A live system could relatively easily pass these steps (e.g., with a new e-signature applied to the records after migration) but only static representations can be safely archived.

Schering-Plough appreciates the opportunity to comment on this draft guidance document and we look forward to issuance of the final guidance document.

Sincerely,

Gretchen Trout
Director, Regulatory Relations and Policy
Worldwide Regulatory Affairs